Infusomat® P

Instructions for Use

Software IFPE / IFPe

B BRAUN

Patient Safety

Attention: Consult accompanying documents! ⚠

Read Instructions for Use prior to use. Application only under regularly supervision by specially trained staff.

Operation

➤ Ensure the unit is properly positioned and secured.
➤ Prior to use check audible and visual alarms during self test. Also check the device for possible damage.
➤ If staff call is used we recommend to check the equipment once after connecting the pump.
➤ Connect to patient only after switching on the device. Interrupt the connection during changing administration set(s) to prevent incorrect dose delivery.
➤ Select cannula/catheter suitable for use with the intended medical application.
➤ Position the infusion line free of kinks.
➤ Recommended change of disposables after 24 h (consider national hygiene regulations).
➤ Compare displayed value with entered value. Start infusion only if values are corresponding.
➤ Installation in medically used rooms must comply with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC-publications.
➤ Possible explosion hazard if used in presence of flammable anaesthetics!
➤ Air in line cannot be detected by the air detector at stop-cocks, infusion ports and additional administration set components.

Other components

➤ Variations in pressure (e.g. as caused by change of level) can affect the accuracy of the device.
➤ Where several infusion lines are connected on one single vascular access the possibility of their exerting a mutual influence vice-versa cannot be excluded.
➤ Refer to respective manufacturer's information for possible incompatibilities of equipment resp. drugs.
➤ Use only compatible combinations of equipment, accessories, working parts and disposables.
➤ The use of not recommended resp. incompatible disposables may influence the technical specification.
➤ Connected electrical equipment must comply with the relevant IEC/EN-specifications (e.g. IEC/EN 60950 for data-processing equipment). The user/operator is responsible for the system configuration if additional equipment is connected. The international standard IEC/EN 60601-1-1 has to be taken into account.

Safety Standards

The Infusomat® P satisfies all safety standards for medical electrical devices in compliance with IEC/EN 60601-1 and IEC/EN 60601-2-24.
➤ The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) maintain the recommended protective distances for these devices. Under certain conditions malfunctions may occur which lead to a device alarm with permanent alarm tone (see also alarm conditions, page 13). Interferences may occur e.g. at electro-magnetic fields > 10 V/m resp. electro-magnetic discharges > 8 kV.

⚠ Special Function "without drip control", see page 10.

Infusomat® P

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*) Technical Safety Check

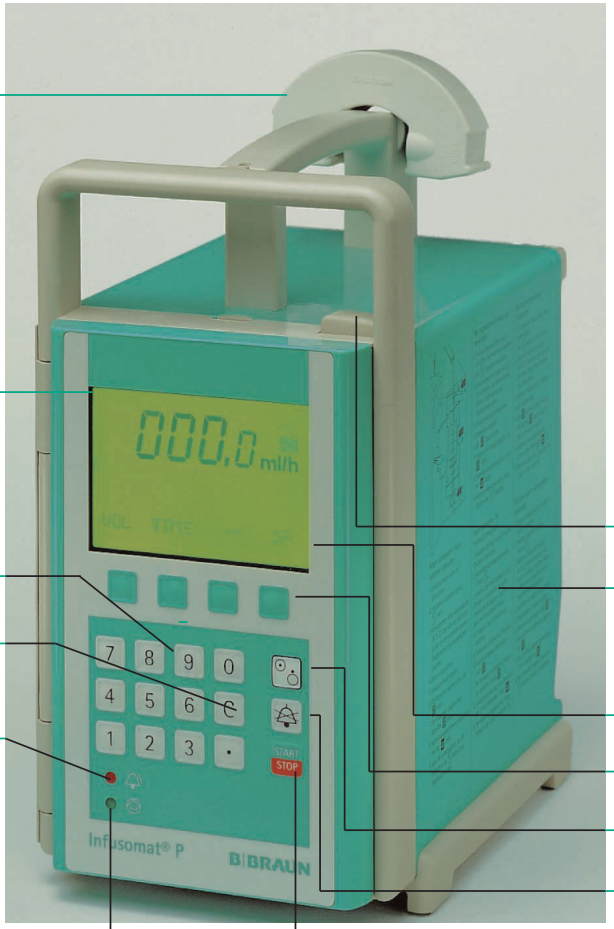
The Infusomat® P is a volumetric infusion pump for application of liquids in infusion and nutritional therapy.

The medical specialist has to decide on the suitability of the application. The decision has to be made on the basis of the warranted properties and technical data.

For further details please refer to the Instructions for Use.

Overview

Handle
For easy transport.



Display
All important information in plain text. Green background illumination only if connected to mains or a key is pushed at battery operation.

Keypad for Input

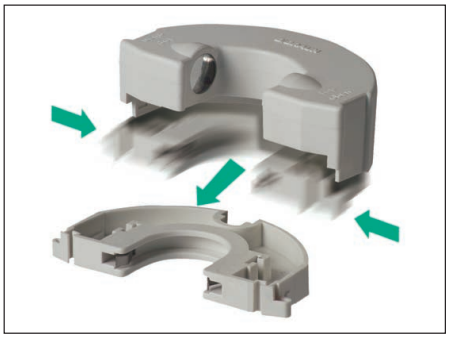
Correct Input/CLEAR
Display reset to 000.0

Red LED indicates alarm condition
Additionally "AAA.A" is flashing in the display. Possible alarms: "drop alarm, air alarm, pressure alarm, pump-door open, battery alarm, standby-alarm"

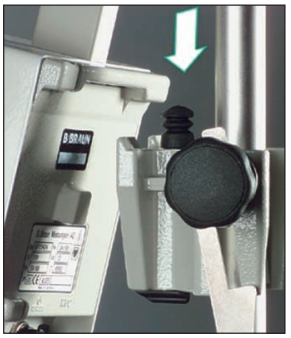
Operating Indicator
Additional operating control indicator in display.

Holder for Drop Chamber
Prevents unintended movement (swaying).

Adapter for Drop Sensor
Replaceable, depending on drop chamber size. Press lateral and pull off.



Universal Pole Clamp
Attach the Infusomat® P from above, clicking into its place. To release, press the black button.



Guide for Short Infusion Pole

Mains/Power Connection
(protect against ingress of moisture). In case of mains/power failure, the pump switches to battery operation. Battery operation time: > 3.0 h at highest delivery rate. Automatic overload protection. Mains fuse: directly above the mains/power connector.

Potential Equalisation
To be connected for ♥ CF-applications.

Mains/Power Supply
For operation with fluid manager system.

Door Opener

Aluminium Housing
Easy-care, drip water protected, resistant to disinfectants.

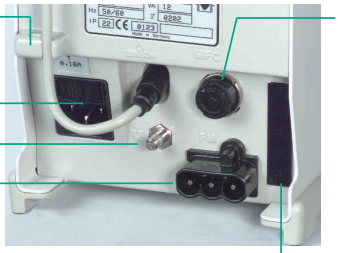
Special Functions "SF"

Function Keys (Soft keys)

Mains/Power Switch ON/OFF

Suppress alarm tone for 2 min

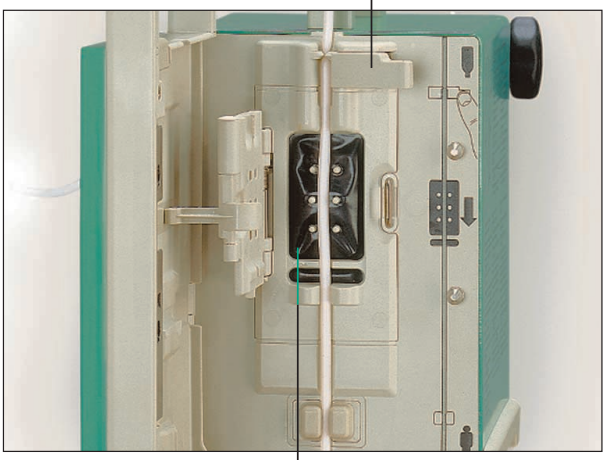
Infusion START/STOP



Multi-Function-Connector (MFC)
Connection for staff call, ambulances (12 V DC) and interface for fm anaesthesia/fm intensive.

Optical Interface
Infrared Interface for operation on "fluid manager system".

Flow Inhibitor (Free flow clamp)
Opening door clamps off infusion line automatically.



Peristaltic Pump
For precise and reliable dosage.

Function Keys

VOL Infusion Volume
Press key below **VOL**. Enter volume (0.1 ... 9999.9 ml). Confirm. Press again key below **VOL**.

TIME Infusion Time
Press key below **TIME**. Enter time e.g. 50 min as 5 0 or 2 h 30 min as 2 3 0. Confirm. Press again key below **TIME**.

RATE Delivery Rate
Only active when rate is calculated automatically. The key below **RATE** confirms the calculated rate.

SF Special Functions
If activated: dose calculation / bolus function / standby / drug selection / occlusion pressure / drop control / piggyback / battery capacity / data lock / loudness / contrast / date, time.

Operation

Infusion

1. Ensure reliable installation

Never position infusion bottle below pump level.

➤ Connect staff call.

➤ Insert spike vertically into infusion bottle.

Fill lower part of drop chamber to max. 2/3.

➤ Open roller clamp.

2. Filling and Venting

Fill infusion line from bottom to top.

➤ Close roller clamp.

3. Switch On with ◯/⦿

Green mains/power control or yellow battery control, alarm tone and display LED's are briefly activated.

Displayed type of infusion line must be identical to the used infusion line. Confirm with "YES".

IFPE: Change of type infusion line is possible if function is activated via Service. Only in this case "NEXT" appears for selection of the type of infusion line.

4. Insert Infusion Line

Press door opener.

➤ Insert infusion line: First locate in free flow clamp, then insert vertical to bottom and fit properly into the air sensor.

➤ Keep infusion line in place at air sensor.

➤ Close door.

➤ Open roller clamp completely. There may not be a continuous drip.

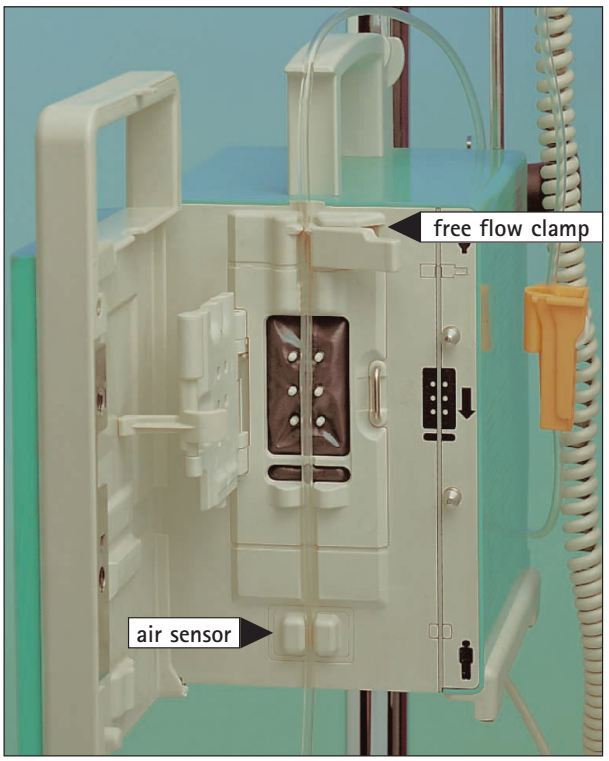
➤ Place drop sensor on drop chamber (if necessary, use an appropriate adapter).

5. Puncture

6. Setting the Delivery Rate

In the range: 0.1 - 999.9 ml/h (IFPe in the range: 0.1 - 600.0 ml/h) and check (selectable in 0.1 ml/h-increments).

Correction: Press **C**, then set new rate. Select additional settings, if desired (see page 9).



7. Press START

Operating symbol appears on the display and the green operating indicator lights.

8. Stop the infusion

➤ Press **STOP**. Green operating indicator goes out

➤ Close roller clamp.

➤ Press door opener. Infusion line will be clamped off when opening the door.

➤ Remove infusion line after pressing free flow clamp. - Replacement: Insert new infusion line as described. Then press **START** again.

➤ **To end switch off**

Press ◯/⦿ for 2 sec.

Additional Settings

To Change the Delivery Rate

➤ Press **START/STOP**.
Green operating indicator goes out.
➤ Press **C**.
Display reset to 000.0

➤ Enter new delivery rate. (No setting possible, when C has not been pressed.).

➤ Press **START/STOP** to restart infusion. (Alarm if no restart within 2 min).

To Change the Rate Without Interrupting the Infusion (Function can be deactivated by Service staff)

➤ Enter new rate.

➤ Press key below **RATE**. Rate is transferred to the upper level as large numbers.

➤ Pump operates at new rate. (If new rate is not confirmed within 10 sec, infusion continues at previous rate.)

Target Volume (Volume Pre-selection)
The target volume will be administered independent on the infused volume.

➤ Press key below **VOL**.

➤ Enter target volume via keypad and confirm with **VOL**. Values between 0.1 and 9999.9 ml. After confirming the display shows the residual volume instead of the target volume.

Note:

When target- / residual volume has been administered, the device switches to KOR-mode. Stop pump and press **VOL**. Clear displayed residual volume with **C** (in display appears target volume **----,-** ml) and confirm with **VOL**. If desired, enter new target volume.

To continue infusion, the target volume has to be displayed as **----,-** ml or a new target volume has to be set.

Target Time (Time Pre-selection)

➤ Press key below **TIME**.
Enter target time via keypad (50 min = 50; 2 h 30 min = 2 3 0).

➤ Confirm: Press key below **TIME** again, instead of the target time the residual time is displayed now.
➤ **Correction**
Press **C**. Display **--h--m**. New entry.

Note:

When pre-selected time has been expired, the device switches to KOR-mode. Stop pump and press **TIME**. Clear resid. time with **C** (in display appears target time **--h--m**) and confirm with **TIME**.
If desired, enter new target time. To continue infusion, the target time has to be displayed as **--h--m** or a new target time has to be set.

Rate Calculation
(Displayed delivery rate must be 000.0)

➤ Enter volume and time.
The delivery rate is calculated automatically and displayed (rounded to one decimal place).

➤ Confirm: Press key below **RATE**.

➤ Start infusion with **START/STOP**.

Clear Time/Volume

➤ Press **STOP**, then key below **VOL** or **TIME**.

➤ Press **C** to clear.
1x: Target Vol/Time = **----.-ml / --h--m**

2x: Infused Volume/Real Time
= **0.0ml / 00h00m**

Additional Settings

KOR-Mode (KVO)
After expiring of the pre-selected time or infusion of the pre-selected volume automatic reduction to keep-open rate (KOR).

➤ KOR and delivery rate flash alternately.
Deactivation and alarm after 30 min.

➤ Switch off with **START/STOP**.

Status request
Only when infusion is running.

➤ Press 1 x resp. 2 x key below **INFO** for actual values.

The display disappears after 10 sec or after all information has been requested.

➤ Press 3 x key below **INFO** for battery capacity in h min and hours of operation.

Special Functions

History Function
In connection with software "IFPE" the Infusomat® P is equipped with a history function (memory of events). This permanent memory records the last 350 events time- and date related:
- Set delivery rate
- Changes of the rate
- Switching on/off
- Start/Stop of infusion
- Remote Control
- Operating and device alarms

At the moment of an event also the volume infused from switching on is recorded.
The history function is activated ex works.
After a software-update the function has to be installed again (service programme: menu 560 calibration history card). With this programme the function also can be deactivated. A faultless time-related recording requires exact setting of time and date.

Recording the data:
The protocol of events only can be transferred to a computer via interface (MFC interface lead). For this a terminal programme installed in the computer has to be selected (settings: 9600 baud, 1 start – 8 data, 1 stopbit).

For the data transfer the Infusomat® P has to be switched off and connected to mains.
The protocol can be requested with key "##" and begins with the latest event. Data are screened in the terminal programme of the computer.
To stop data transfer: Press key below END.

The history function mainly is used for failure analysis for the technical service. A data transfer via fm system is not possible.

Special Functions

Select Special Mode SF
Depending on the version, several functions may be deactivated. Contact service.

➤ To set special functions press key below **SF** repeatedly until desired special function is displayed. – Then follow Instructions for Use as described.

Activate Bolus Function
For additional boli.

➤ Pressing key below **ON** activates the function (function is maintained after switching on again).

To change bolus rate:

➤ Press key below **RATE**. Enter new value and confirm.

Correction: Press **C** and re-enter.

Exit bolus function:

➤ Press key below **END**.

Bolus application during infusion:

Bolus with volume pre-selection

➤ Press key below **BOL** and release.

Display: BOLUS RELEASE?

➤ Enter bolus. Values between 0.1 and 99.9 ml (if no entry is made within 10 sec function is exited automatically).

➤ Press key below **YES**. Bolus is administered. After the bolus application the infusion continues at basic rate.

To stop bolus:
➤ Press key below **STOP**.

Bolus without Volume Pre-selection

➤ Press and hold **BOL** until a second BOL is displayed.

➤ Hold both **BOL**-keys. Bolus is administered as long as both keys are pressed. Per ml bolus administered a short audible signal sounds.

Interval bolus
Automatic bolus in set time interval. In case of manual bolus administration the interval bolus is skipped.

➤ Select bolus function under **SF**.

➤ Press key below **VOL**, **TIME** or **RATE**. Enter values and confirm. After value below **TIME** has been confirmed, interval times runs automatically. Exit function with **END**, set basal rate and start. Remaining interval time is displayed in h:min:sec.

A bolus on demand is possible at any time during infusion at basal rate.

Bolus and dosage calculation
➤ Operation as in volumetric mode.
Depending on the settings in ml (volume), quantity of active agent (e.g. mg) or in quantity of active agent per kg weight (mg/kg) the bolus may be administered. During bolus administration all three values are displayed.

Standby/Pause
In case of extended interruptions set values are retained.

➤ Press **STOP**.

➤ Press key below **SF** until "Standby" is displayed.

➤ Press key below **ON**.

➤ Enter length/duration of interruption interval or confirm time displayed.

Correction: Press **C**. Display 00h 00m.
New entry.

➤ Confirm **TIME**. Timer for interruption on display is running. Alarm at the end of interruption interval.

➤ End of interruption interval: Press key below **END**.

Special Functions

Drug Display
9 selectable drug names can be stored (input via service program only).

➤ Select with key below (+). Drug is displayed, also during infusion.

➤ Key below **CLR** deletes drug name from display.

➤ Exit selection: Press key below **END**.

Occlusion Pressure
Due to variable pressure limits shortened alarm times are possible. Occlusion pressure high/low. See Technical Data.

➤ Select pressure with key below (+) or (-).

➤ Exit selection: Press key below **END** (select pressure as low as possible).

Switch off Drop Control
Caution:

– No alarm will be emitted if the drop control is switched off and the roller clamp is closed (underdosage).

– No alarm will be emitted in case of occlusion within the infusion line and pressure sensor fails.

– Drop control may only be switched off where underdosage is not critical for the patient or where the patient is maintained under constant observation.

Operation without drop control only with volume pre-selection:

➤ Set infusion volume.

(The volume in the infusion bottle has to be sufficient!).

➤ Press key below **SF** as many times as necessary for "drop control" to appear.

➤ Press key below **OFF**. "no drop control" appears.

➤ To switch on again: Press key below **ON**.

➤ Exit from selection: Press key below **END**.

Check Battery Capacity
Remaining battery life time is displayed, e.g. battery capacity = 02 h 30 min.
In addition the operating hours are displayed.
To switch off display again: Press key below **END**.

➤ With device switched off and mains/power lead detached: Briefly press ◯/⦿. Short display of remaining battery life time after 3 sec. -

Device switched off and mains/power lead connected: Permanent display of remaining battery life time.

Battery replacement is recommended if a remaining life time of less than 2 h is displayed after 16 h charging time.

Data Lock
Interlocks keys to prevent unauthorised use.

➤ Press key below **ON**. Keys are interlocked.
➤ Key release: Press decimal point key, then key below **END**.

Loudness control of alarm tone (only software IFPE)
The loudness of the audible alarm can be adjusted in 9 steps.

➤ Increase with key below (**+**) resp. decrease with key below (**–**).

➤ Exit selection: Press key below **END**.

Set Date/Clock
➤ Set date: Press key below **DAT**, enter date and confirm with **DAT**.

➤ Set time: Press key below **TIME**, enter time and confirm with **TIME**.

➤ Exit selection: Press key below **END**.

Dosage Calculation (Overview)
The dosage calculation automatically calculates the delivery rate in ml/h.

Setting parameters:

1. Concentration
   - per ml or
   - quantity per volume of infusion bottle.

Entry: mcg, mg, IU or mmol, each from 0.001 to 99999 (5-digit, decimal point counts as one digit).

2. Selection for weight- and time-related or only time-related dosage. Entry of body weight: from 0.01 kg to 200 kg.

3. Entry of dosage:
   a) Weight- and time-related in mcg/kg, mg/kg, IU/kg, mmol/kg, each per /min, /h or /24 h.
   b) Only time-related in mcg, mg, IU or mmol, each per /min, /h or /24 h.

Dosage Calculation (Operation)
➤ Press key below **SF** repeatedly until DOSAGE CALC.OFF appears.

➤ Press key below **ON**.

➤ Select quantity unit.

Select with key below mcg.

Note: After numerical entry change of quantity unit is not possible anymore.

(Remedy: delete numbers).

➤ Enter concentration by moving flashing star to desired entry position with arrow keys. Confirm all numbers with **OK**.

Entry of concentration per 1 ml or per volume of infusion bottle.

➤ For dosage by body weight enter body weight and confirm. Otherwise confirm 0 kg.

➤ Select desired quantity- and time unit.

➤ Enter values (at flashing star as described) and confirm with **OK**. Automatically calculated values (rate or dosage) are displayed.

➤ First check rate displayed for plausibility, then confirm **RATE**. Value is displayed.

➤ Start infusion.

Note: Dosage value with unit is displayed (down on the right). As the automatically calculated value of the rate is rounded, the dosage value may change insignificantly.

Info Request
➤ Press key below **INFO**.

1x: Infused Volume, Run Time
2x: Infused Volume, Actual Volume
3x: Battery Capacity, Operating Hours.

Change Rate / Dosage
➤ Press **STOP**.
➤ Enter new dosage value and confirm with **RATE**.
➤ Start infusion again.

Change Rate or Dosage without Interruption of Infusion
During infusion a star is flashing down on the right.

➤ Enter new value and confirm with **RATE**.
Pump operates with new rate / dosage.

Note: Alternatively the star can be moved with the arrow key to change the rate in ml/h.

Change Concentration with Dosage Calculation Activated
➤ Press key below **SF** repeatedly until DOSAGE CALC.ON appears and confirm with **OK**.

➤ Press **CLR**.
Concentration is cleared.

➤ Enter new value and confirm.

Change dosage
➤ Press key below **SF** repeatedly until DOSAGE CALC.ON appears and confirm with **OK**.

➤ Change values (move flashing star as described) and confirm entries with **OK**.

Special Functions

➤ Check entered or calculated rate for plausibility and confirm with key below **RATE**. Rate is displayed.

➤ Start infusion.

Switch off Dosage Calculation

The dosage calculation remains activated until it is switched off in Special Functions. If the Infusomat® P is switched off in the meantime all previous values except the body weight are maintained.

Switch off from Basic Menu

➤ Press key below **SF**, display DOSISCALC.ON.

➤ Press DOSISCALC.OFF.

Dosage calculation is deactivated.

➤ With key below **END** back to basic menu.

Piggyback Function

The piggyback-mode offers the possibility to interrupt the current (primary) infusion temporarily in order to administer a piggyback (secondary) medication. Above the pump the piggyback-infusion line is connected with a Y-connector to the administration set. Close clamp of primary infusion.
All infusion lines must be primed.

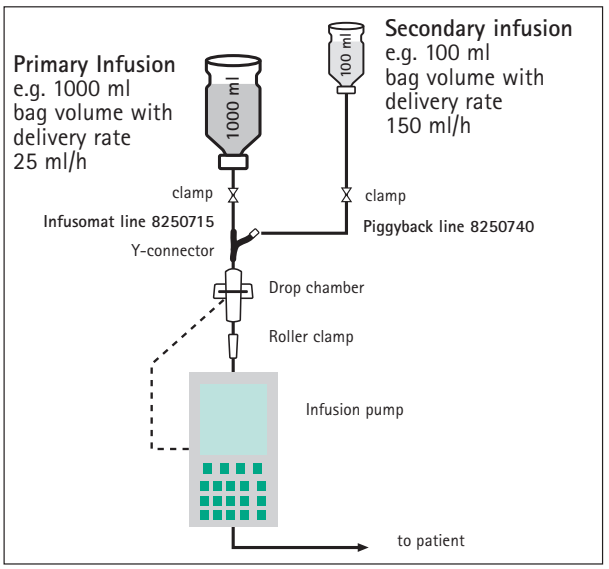
➤ Select Special Function Piggyback with key **SF**.

➤ Key below **ON** activates function (remains active also after switching on the Infusomat® again).

➤ Enter primary rate and volume and confirm. The softkey **PIGY** only will be displayed after a target volume had been entered before.

➤ Press key below **PIGY**, enter piggyback rate and volume and confirm.

➤ Start infusion. Pump delivers the piggyback volume with the set piggyback rate.



As soon as the programmed piggyback volume has been infused, delivery continues with "keep open-rate"(KOR) resp. after 30 min KOR-operation the pump stops and activates an alarm. The operator must switch over to the primary infusion manually. Close clamp of secondary medication and re-open clamp of primary infusion.

Please note: The Piggyback mode requires the input of a target volume resp. a target time for the primary as well as for the secondary infusion. It also is possible to start with the primary infusion (after entering the Piggyback values switch back to primary with **END**). In **STOP** mode it is always possible to switch over between Piggyback and primary mode.

Alarms

Operating alarms

Remedy failure and restart infusion.

Drop Alarm / Pressure Alarm

➤ Infusion bottle empty?

➤ Roller clamp closed?

➤ Flow? – Close roller clamp.
Infusion STOP. There may not be a continuous drip. Insert new infusion line, if necessary.

➤ Occlusion? – Insert infusion line free of kinks and check the free flow (consider bolus).

➤ Condensed drop chamber? Shake to remove.

➤ Drop sensor fitted/connected? Replace drop sensor, if necessary.

Air Alarm

➤ Air in administration set? – Insert infusion line correctly. Vent and reset fluid level in drop chamber.

Standby Alarm

➤ Alarm after pre-selected pause?
Switch to Standby with key below **SF**.
Then end pause with key below **OFF** or extend pause with key below **ON**.

Battery Pre-Alarm

➤ Battery pre-alarm 30 min before battery is discharged:
- Alternately rate and AAA.A are displayed,
- battery indicator flashes,
- audible alarm every 9 sec.

Alarm can be cleared by pressing -key. The alarm continues in short intervals until the battery is fully discharged.

➤ Battery Alarm:
- Alternately rate and AAA.A are displayed.
- The text display shows:
  "battery discharged, connect to mains".
- battery indicator flashes,
- red alarm indicator is on,
- audible alarm every 4 sec.,
- operating indicator off,
- staff call.

➤ Switch off device.
Connect to mains/power or 12 V DC power source.

KOR-Alarm (KVO)

Pre-alarm: audible alarm every 9 sec max. 30 min. End of infusion alarm: Permanent interval signal tone (also via staff call).

Delay of Alarm Tone

➤ When connected to staff call the alarm tone on the device can be suppressed for 10 min. (This function can be activated via service only.)

Further Alarms / Displays

➤ "pump door open"? – Close door.

➤ "invalid rate"? – Enter different value.

Device Alarms

When display indicates "device alarm" an audible alarm sounds permanently.

➤ Press **ON/OFF**-key repeatedly until display indication "do not press any key until display is off". Pump switches off automatically after a few seconds.

➤ Switch on device again.
In case of repeated device alarm inform service.

Alarms

Mains Operation, 12 V DC or Battery

➤ Check mains voltage as per type plate!

➤ Plug in mains/power lead at rear (screw in 12 V DC lead in ambulance car).

➤ In case of mains/power failure or if 12 V DC or mains/power is not connected the unit automatically will be switched to integrated rechargeable battery.

Charge Battery

➤ Charge battery in case of:

- first use
- battery alarm
- non-use > 2 months.

Battery is charged if 12 V DC or mains are connected – even during infusion.

Charging Time

➤ Approx. 16 hours. Longer charging is not detrimental.

Capacity

A fully charged battery is sufficient for more than 3.0 h with highest delivery rate.

Rechargeable Batteries Ageing

After 2 years the original capacity is only approx. 50 %.

➤ The lifetime of the battery can be extended by completely discharging from time to time and recharging afterwards.

Interface

Interface Operation

Connection to interface input via MFC-plug. Interface descriptions available from B. Braun.

➤ **Send Proposal**

The delivery rate and a drug can be entered in the Infusomat® P as "proposal" via an external computer. Both items of data must be checked on the Infusomat® P and acknowledged.

➤ **Remote Control**

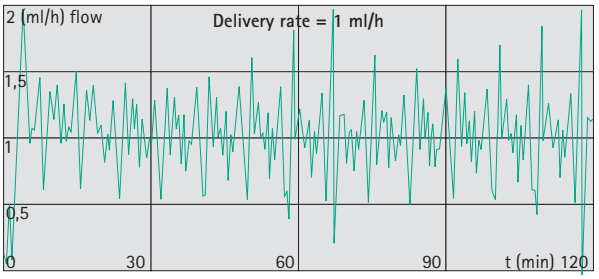
Via fm controller possible. When using a commercially available external computer this must satisfy the requirements acc. to IEC/EN 60601-1 as well as the single-fault fail-safe condition acc. to IEC/EN 60513.

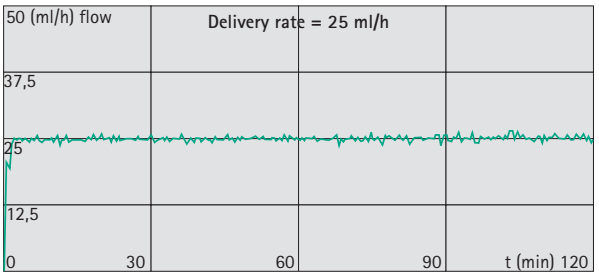
➤ **Documentation**

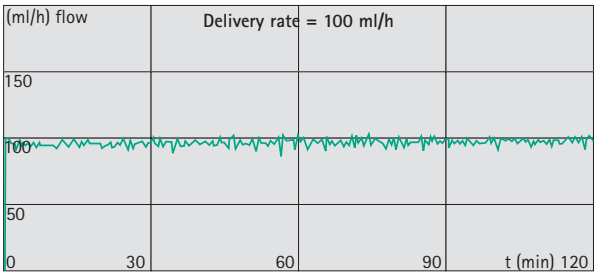
All operating data of the Infusomat® P can be requested and logged via external computer.

Start-up Graphs and Trumpet Curves

Start-up Graphs

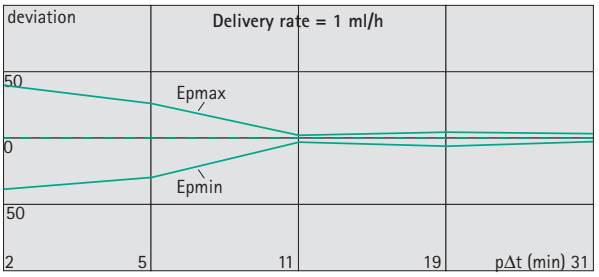


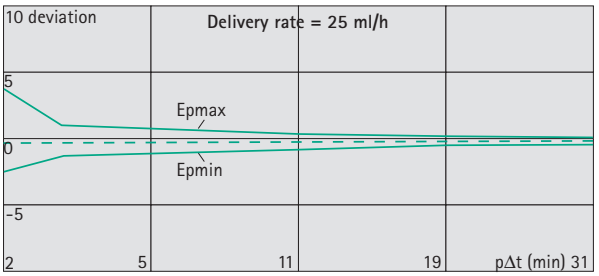


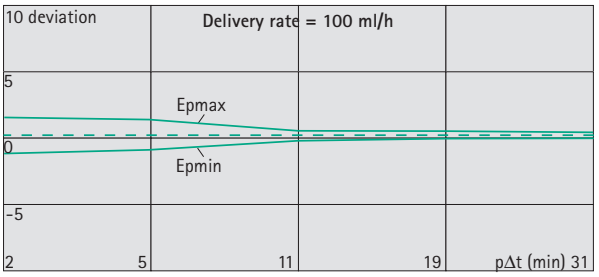


The graphs show the accuracy/uniformity of flow in relation to time. Allow for the following:
The delivery behaviour resp. delivery accuracy is essentially influenced by the types of disposables used.
Significant deviations may be encountered if use is made of disposables others than those stated in the order data.

Trumpet Curves







Trumpet Curves
Measured values for second and last hour in each case.

Measurement interval	$\Delta t = 0.5$ min
Observation interval	p x Δt min

Start-up Graphs

Measurement interval	$\Delta t = 0.5$ min
Measurement duration	T = 120 min
Flow	Q_i ml/h

Technical Data

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	defibrillator-proof, CF equipment Protection Class I; IP 22 (Moisture protection: drip protected)
Class (acc. to Directive 93/42 EEC)	II b
Rated voltage / current	230 V AC~ (0.06 A), 50/60 Hz Mains fuse T 0.16 A or 200 V/230 V/240 V AC~ * (0.06 A), 50/60 Hz Mains fuse T 0.16 A or 100 V/110 V/120 V AC~ * (0.12 A), 50/60 Hz Mains fuse T 0.315 A * Mains voltage can be selected at appliance inlet.
External extra-low voltage	12 V DC ⎓
Staff call	Max. 24 V / 1 A / 24 VA Arbitrary connection polarity (VDE 0834)
EMC	EN 55011 IEC/EN 60601-1-2 and IEC/EN 60601-2-24
Time of operation	100 % (continuous operation)
Operating conditions -Relative humidity -Temperature -Atmospheric pressure	 30 % ... 90 % (without condensation) + 18 °C ... + 35 °C 700 mbar ... 1060 mbar
Storage conditions -Relative humidity -Temperature -Atmospheric pressure	 10 % ... 90 % - 25 °C ... + 55 °C 500 mbar ... 1060 mbar
Battery type (rechargeable)	NiCd (7.2 V; 1.2 Ah)
Operating time of rech. battery	> 3.0 h at highest delivery rate
Recharging time	> 16 h
Weight / Dimensions (WxHxD)	Approx. 3.1 kg / 140 x 240 x 200 mm

Air detector

Technical sensitivity
Air bubbles > 0.01 ml
Alarm triggering: With air bubble size
of typ. 0.3 ml [1)]
(limit value 0.4 ml) or 1.5 ml/h [2)]
(cumulative value of 1 h as of air bubble
volume 0.01 ml)

[1)] Can be set from 0.01 to 0.3 ml via service program only
[2)] Can be set from 0.5 to 3.5 ml/h via service program only

Accuracy of set delivery rate

typ. ± 5 % with Intrafix® P Infusion set,.
measurement time 24 h, temperature 22 °C

Delivery range

0.1 ... 999.9 ml/h (0.1 ml/h-increments)
Software IFPE
0.1 ... 600.0 ml/h (0.1 ml/h-increments)
Software IFPe

Delivery pre-selection

0.1 ... 9999.9 ml (in 0.1 ml-increments)

Occlusion alarm pressures

Alarm reaction time

rate	low app. 0.6 bar	high app. 1.2 bar
1 ml/h	17 min	30 min
25 ml/h	45 sec	72 sec
100 ml/h	12 sec	18 sec
	0.3 ml	0.5 ml

Max. bolus volume
(measured at 22 °C with Intrafix® P set)

Mechanical occlusion pressure limit
under fault conditions

Occlusion alarm pressure max. 3.0 bar (300 kPa)
max. bolus volume 2 ml

Alarm in case of incorrect dosage

In case of incorrect dosage of max. 0.6 ml due
to apparatus malfunction the pump switches off
automatically.

KOR-rate (KVO)

Delivery rate > 10 ml/h = 3 ml/h
Delivery rate < 10 ml/h = 1 ml/h
Delivery rate < 1 ml/h = STOP

Warranty / TSC*) / Service / Cleaning

Responsibility of the Manufacturer

The manufacturer, assembler, installer or importer considers himself responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorised by him,
- the electrical installation of the relevant room complies with the appropriate requirements (e.g. VDE 0100, 0107 and/or the IEC-publications resp. national requirements),
- the equipment is used in accordance with the Instructions for Use and
- the Technical Safety Checks are carried out regularly.

The CE mark confirms that this medical product complies with the "Council Directive on Medical Devices 93/42/EEC" dated 14th June 1993.

B. Braun Melsungen AG

Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Infusomat® P. This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects. Modifications or repairs to the unit undertaken by the owner or by third parties invalidate the warranty.

The warranty does not cover the following: Elimination of faults attributable to incorrect/inexpert handling, or to normal wear and tear and rechargeable batteries.

Technical Safety Check*) / Service

The Technical Safety Check is recommended to be carried out every 2 years and should be documented.
Servicing work must be carried out exclusively by personnel instructed by B. Braun.

Check regularly

Check for cleanliness, completeness and damage. Use only according to Instructions for Use. Check each time when switching on: self-check, audible alarm, process- and alarm control indication.

Cleaning

Clean using mild soap suds. Do not use spray disinfectants at the mains power connection. Recommended: disinfectant for wiping available from B. Braun (e.g. Meliseptol®).
Before operation the device allow to vent for at least 1 min. Do not spray into openings in the device. Be sure to observe the instructions provided concerning waste disposal and hygiene for batteries and disposables.

Inspection on Delivery

Despite careful packaging, the risk of transport damage cannot be entirely prevented. Upon delivery, please check that nothing is missing. Do not use a damaged device. Contact the service department.

Items included

Infusomat® P, Power Cord, Drop Sensor, Pole Clamp, Instructions for Use.

Ordering

	Art.-Nr.
Infusomat® P 230 V	871 2379
Infusomat® P 200 – 240 V	871 2212
Infusomat® P 100 – 120 V	871 2387
Recommended accessories for Infusomat® P	
Connecting lead for potential equilization	870 1628
MFC-Connecting lead for staff call	871 1682
MFC-Connecting lead for ambulance car (12 V)	871 1674
MFC-RS 232 interface cable with electrical isolation	871 1661
Short stand with drop chamber holder	870 1644
Universal clamp fm	871 8474
Universal clamp, rotating	871 8482
Universal adapter for drop sensor	871 1747
Without air vent:	
Intrafix® P, 180 cm, sil. spike	407 0038
With air vent:	
Intrafix® Air P, 150 cm	406 2957
Intrafix® Air P, 180 cm	406 2981
Intrafix® Air P, 150 cm, sil. spike	409 2930
Intrafix® Air P, 180 cm, sil. spike	406 2990
Intrafix® Air P, RV, 150 cm	406 3252
Intrafix® Air P, RV, 180 cm	406 3287
With automatic air vent:	
Intrafix® Air-Matic P, 150 cm	406 3953
Intrafix® Air-Matic P, 180 cm	406 3988
Intrafix® Air-Matic P, 180 cm, sil. spike	406 2973
Intrafix® Air-Matic P, 200 cm, sil. spike	406 3007
Intrafix® Air-Matic P, RV, 150 cm	406 3759
Intrafix® Air-Matic P, RV, 180 cm	406 3783

Other infusion lines upon request.

B BRAUN
HOSPITAL CARE

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